



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/719,602

11/21/2003

Samantha K. Holme

(020001)-07-LAV

3118

7590 01/21/2010
ALLEN R. KIPNES, ESQ.
WATOV & KIPNES, P.C.
P. O. BOX 247
PRINCETON JUNCTION, NJ 08550

EXAMINER

ROBERTS, LEZAH

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

01/21/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/719,602	Applicant(s) HOLME ET AL.	
	Examiner LEZAH W. ROBERTS	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,9-16,18-22,24,26-30,33,36,39,40 and 42-46 is/are pending in the application.
- 4a) Of the above claim(s) 15,16,18,19,26-28 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,9-14,20-22,24,29,30,33,39,40 and 42-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed October 2, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejections)

1) Claims 1, 2, 9, 10, 13, 14, 20-22, 24, 29, 30, 33, 39, 42 and 43 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Chaykin (US 6,013,274) in view of Witzel et al. (US 4,238,475) in further view of Sagel et al (6,582,708).

Applicant's Response

Applicant argues Chaykin does not disclose chewing gums and actually teaches away from chewing gums. Chaykin teaches edible oral cleansing and sanitizing compositions that contain three classes of cleansing and sanitizing agents, namely surfactants and protein flocculators. Chewing gum compositions cannot be swallowed.

Art Unit: 1612

Witzel does not teach peroxides or surfactants as active agents and does not provide any teaching that would complement Chaykin. Sagel does not disclose chewing gums, and teaches in order to stabilize peroxides, the peroxides must be placed in a thin film strip, thus teaching away from chewing gum.

Examiner's Response

Contrary to Applicant's arguments, Chaykin does in fact teach chewing gums (col. 4, lines 31- 36 and Formulation #6). Therefore the reference does not teach away. In regard to Witzel et al., it discloses encapsulating active components in order to facilitate release from a chewing gum. Encapsulation inhibits the active from being bound to the gum base. Thus it would have been obvious to encapsulate the cleansing agents, as well as the peroxides of Sagel to facilitate their release from the chewing gum. Although Sagel discloses incorporating peroxides into films, it also discloses the peroxides are the most common dental bleaching agents and may be encapsulated in order to stabilize them. Not only would one of ordinary skill in the art incorporate the peroxides for their known function, one of ordinary skill in the art would recognize that encapsulating the peroxide when used in chewing gum would not only stabilize them but also facilitate their release as supported by Witzel et al. Thus the instant claims are obvious over the combination of references.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejections)

1) Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chaykin (US 6,013,274) in view of Witzel et al. (US 4,238,475) and Sagel et al (6,582,708) as applied in the rejection above, in further view of Kleber et al. (US 5,064,640).

Chaykin, Witzel et al. and Sagel et al. have previously been discussed and differ from the instant claims insofar as they do not disclose sodium stearate although they teach fatty acids and their water soluble salts.

Kleber et al. is used as general teaching disclosing sodium stearate is an anionic surfactant used in oral compositions. The reference differs from the instant claims insofar as it does not disclose the compositions of the instant claims.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to have used sodium stearate in the compositions of the combined teachings of Chaykin, Witzel et al. and Sagel et al. motivated by the desire to use a water soluble fatty acid salt disclosed to be used as an anionic surfactant in oral compositions as disclosed by Kleber et al. and supported by MPEP 2144.07.

2) Claims 43-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chaykin (US 6,013,274) in view of Witzel et al. (US 4,238,475) and Sagel et al

Art Unit: 1612

(6,582,708) as applied in the rejection above, in further view of Cherukuri et al (4,980,178).

Chaykin, Witzel et al. and Sagel et al. have previously been discussed and differ from the instant claims insofar as they do not disclose the gum is a center-filled gum.

Cherukuri et al. disclose center-filled gums may be used to deliver pharmaceutical components and depending on the form of the component, the release of the pharmaceutical may be controlled. The pharmaceuticals are incorporated into the liquid center of the gum in the desired form. (col. 15, lines 10-30). The reference differs from the instant claims insofar as it does not disclose the pharmaceutical components are peroxide, polyphosphate or an anionic surfactant.

It would have been obvious to one of ordinary skill in the art to have used center-filled gums to deliver the active ingredients in the compositions of the combined teachings of Chaykin, Witzel et al. and Sagel et al. motivated by the desire to obtain the desired rate of delivery of each active by having them enclosed in the center of the gum, as disclosed by Cherukuri et al.

3) Claims 1, 2, 9, 13, 14, 20-22, 24, 29, 30, 33, 39, 40 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hill (US 5,380,530, already of record) in view of Miskewitz (US 5,693,334).

Hill discloses an oral hygiene preparation including plaque disrupting and gingivitis control preparations in the form of chewing gums, wherein the chewing gum is coated with a plaque disrupting emulsion containing an ingestible surfactant and a

Art Unit: 1612

polydimethyl siloxane. The coating may further contain a therapeutic substance (Abstract). Surfactant cleansing removes food debris and staining substances (col. 1, lines 54-57). The release of active ingredients from the gum base is a major problem (col. 8, lines 63-68). It is also disclosed that it is a usual practice in the industry when manufacturing chewing gums having active ingredients to deposit the active ingredient upon the exterior of a gum nugget or center. The use of candy coated gum allows for the dissolution of the active ingredient in the mouth before it is chewed into the gum base (col. 9, lines 1-5). Surfactants include sodium lauryl sulfate, encompassing claim 9, and a salt of a fatty acid (reference claim 9). The coatings may also include various antimicrobial agents (col. 15, lines 20-23).

The reference differs from the instant claims insofar as it does not disclose the compositions comprise peroxide.

Miskewitz disclose chewing gums with dental benefits. The compositions comprise two or more active ingredients to improve dental health. The compositions comprise a gum base, encapsulated bicarbonate, a peroxygen compound, a bulking sweetener and a flavorant (Abstract). The peroxygen ingredient provides anti-bacterial activity and is beneficial for alleviating the distress associated with gingivitis and periodontitis inflammatory disorders (col. 7, lines 35-37). Peroxygen compounds include urea peroxide, alkaline earth metal peroxides and alkali metal peroxides (col. 5, lines 34-46), encompassing claim 2. The peroxygen compound comprises 0.5 to 12 weight percent of the chewing gum composition (col. 3, lines 26-30), encompassing claims 20-22. The compositions may also comprise surfactants such as sodium lauryl

Art Unit: 1612

sulfate. Surfactants are used to enhance the flavor and to enhance the compatibility of the ingredients in the chewing gum. These are incorporated into the gum ranging from 0.001 to 3 weight percent of the compositions (col. 6, lines 43-53), encompassing claims 13 and 14. Other surfactants are incorporated by reference US 3,930,026 (This reference, Clark, discloses the flavoring is mixed with a surfactant and absorbed on a hydrophilic colloid such as gum arabic and ethyl cellulose, col.2, lines 5-7) (col. 6, lines 63-65). The flavorant may be encapsulated (col. 6, lines 23-25). The encapsulating agents used include gums and polymers (col. 5, lines 9-20), encompassing claims 29 and 30.

The reference differs from the instant claims insofar as it does not specifically disclose the surfactants are not materially bound to the gum base.

It would have been obvious to one of ordinary skill in the art to have incorporated a peroxygen compound as an antimicrobial in the coatings of Hill motivated by the desire to use a compound that has antibacterial activity and is beneficial for alleviating the distress associated with gingivitis and periodontitis inflammatory disorders, as disclosed by Miskewitz.

In regard to claim 29, when the peroxide is incorporated into the coatings of Hill, they are considered to be encapsulated because they are encapsulated within the coating, thus meeting the limitation "comprising an encapsulating substance for encapsulating the peroxide compound".

Alternatively, it would also have been obvious to have encapsulated the peroxygen compound and encapsulated the surfactant with the flavorant in the

compositions of Miskwitz motivated by the desire to inhibit the actives from being bound by the gum base thus facilitating their release from the gum as disclosed by Hill.

Allegation of Unexpected Results

Applicant's Alleged Unexpected Results

Applicant's argues there is no reasoning asserted as to why other surfactants and peroxides would not be expected to yield the same or similar results. Applicants therefore submit that the results submitted are good enough and complete enough to support the present claims as amended.

Examiner's response

As previously stated, it cannot be determined from the results disclosed by Applicant that all anionic surfactants and peroxides at all concentrations will yield similar results. Considering that Applicant does not appear to make any explanations or theories as to why the results were obtained, there is no way to predict that all surfactants and peroxides will interact with one another in the same way. Especially in the case of anionic surfactants, which is a huge genus comprising compounds of varying structures. It is reasonable to conclude that these surfactants have divergent functions and thus not all anionic surfactants will interact with different peroxides in the same way. Therefore it cannot be predicted if all combinations of anionic surfactants

and peroxides at all concentrations will yield the asserted unexpected results based on the evidence provided by Applicant.

Claims 1, 2, 9-14, 20-22, 24, 29, 30, 33, 39, 40 and 42-46 are rejected.

Claims 15-16, 18, 19, 26-28 and 36 are withdrawn.

No claims allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612